

REMARKS

Claim Status

Claims 1-28 are pending. Claims 1-28 were rejected.

Double Patenting

Claims 1-18 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/125,367. The examiner feels that although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to compositions comprising electrolytes, carbohydrates and low water content. The formulation when concentrated has a Brix between 78-85, and water content below 5%. The formulation of the instant claims is broader than that of the '367 application in that the claims are silent to fiber, protein and starch hydrolysate content, however the instant claims are written with open claim language. The compositions of the '367 application would obviate the instant claims if allowed.

The applicant respectfully disagrees with the examiner. Primarily, the instant invention is patentable over the applicant's prior application. More specifically, in the instant application the applicant claims an oral rehydration composition that comprises water and **an effective amount of liposomed electrolytes**. There is no teaching or suggestion in the applicant's prior application of including an effective amount of liposomed electrolytes. This difference is critical to the instant invention and is patentably distinct from the prior application in that it is new, useful and non-obvious over the prior application (an any known prior art).

Accordingly, the applicant respectfully requests that the examiner withdraw the instant rejection.

Claim Rejections – 35 U.S.C. § 102

Claims 1-13, 15, 17, and 19-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Takaichi et al (USPN 5,455,235 hereafter '235). The claims are drawn to a composition comprising liposomed electrolytes. The claims are drawn also drawn to a method for orally rehydrating a subject comprising drinking the oral rehydration solution comprising liposomed electrolytes.

The examiner feels that the '235 patent teaches an oral formulation comprising liposomed electrolytes (in the abstract). The formulation comprises electrolytes such as magnesium potassium and calcium salts (col. 4, un. 20-35). The liposome includes soybean phospholipid (cot. 6, un. 40-45). The formulation has an osmolality from 200-270 mOsmols (col. 4, tin. 10-19). The formulation further comprises vitamins, flavors and amino acids (col. 5, lin. 35-40). Vitamins include vitamin E, C and retinal (col. 5, un. 5 1-55, cot. 7, un. 25-30), amino acids such as sodium glutamine, glycine (cot. 5, lin. 38) and flavors include grapefruit, orange lemon and pineapple (co. 5, lin. 35). The water content of the formulation is about 0.8% in a concentrated form (cot. 10, un. 10-18). The formulation is rehydrated with an amount of water and delivered to the subject (col. 8, un. 60 67). The ingredients are combined and homogenized in order to arrive at the concentrated form (col. 7, lin. 55-60).

The applicant respectfully disagrees with the examiner.

Before dealing with the specific rejections and references, let us begin by dealing with the law of anticipation as it currently stands. Anticipation is the complete disclosure in a single prior art source of a device substantially identical to the claimed invention. Harris v. NRM Corp., 191 USPQ 643 (1976, ND Ohio). An invention is anticipated when “all of the same elements are found in exactly the same situation and united in the same way to perform the function in a single prior art reference.” Schroeder v. Owens Corning Fiberglas Corp., 514 F2d 90, 185 USPQ 723 (1975, CA9 Cal). (Citing Walker v. General Motors Corp. (CA9 Cal) 362 F2d 56, 58, 149 USPQ 472, 473, 474. An invention is not anticipated when the alleged anticipating device is substantially different in construction and operation from the claim invention. Fuller v. Yentzer, 94 US 299, 24 L. Ed. 107 (1877).

In the present matter, the instant application claims water and **an effective amount of liposomed electrolytes**. While water is ubiquitous, liposomed electrolytes are not. In fact Takaichi ‘235 merely discloses a phospholipid for use in dissolving carotenoid. Thus the phospholipid is a solvent for oil-soluble materials and not a lipid containing effective amounts of electrolytes. Therefore, Takaichi ‘235 fails to disclose “all of the same elements ... found in exactly the same situation and united in the same way to perform the function in a single prior art reference.”

Accordingly, the applicant respectfully requests that the examiner withdraw the instant rejection.

Claim Rejections – 35 U.S.C. § 103

Claims 1, 10-12, 14, 16, and 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Andon et al (USPN 5,468,506 hereafter '506). The claims are drawn to a composition comprising liposomed electrolytes and water, and a concentrated form of the composition.

The examiner feels that the '506 patent discloses a composition comprising phospholipids, electrolytes, and a low concentration of water (abstract). The composition comprises phospholipids such as lecithin (col. 8, lin. 5) and electrolytes such as ionic calcium salts (col. 6, lin. 64-col. 7, lin. 13; col. 8, lin. 8-65). The water content of the formulation can be kept low, below 20% (col. 11, lin. 65-col. 12, lin. 28). This low water content provides a viscous syrup comprising high fructose corn syrup having a Brix of 77 (col. 6, un. 15-25). The formulation is homogenized (cot. 11, lin. 65- col. 12, lin. 28).

The examiner feels that the formulation differs from the instant claims in the water content. The '506 patent discloses a low water content of below 20%, while the instant claims have a water content below 10%. This is a result effective parameter that can be optimized through routine experimentation by those of ordinary skill in the art. The claims require the formulation to be concentrated, presumably removing the water content resulting in a viscous syrup with the resultant Brix value.

The syrup of the '506 patent comprises a Brix of 77 and a low water content. The examiner feels it would have been prima facie obvious to lower the water content in order to further concentrate the syrup in order to reduce the size or increase the potency of the product. Where the general conditions of a claim are disclosed in the prior art, it is not

inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. See *in re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).


The applicant respectfully disagrees with the examiner. Andon '506 discloses a sweetener supplement. However, Andon '506 does not disclose liposomed electrolytes. While Andon '506 discloses electrolytes, the cited disclosure of the electrolytes being liposomed are missing. The examiner points to the abstract as containing a disclosure of phospholipids. This disclosure is, unfortunately, not there. While the examiner also points to col. 8 line 5 as disclosing lecithin (a phospholipid), that disclosure, like Takaichi discloses the lecithin as an emulsifier and not as a liposome containing electrolytes.

While Andon '506 discloses electrolytes, as previously stated, there is no teaching or suggestion of encapsulating these electrolytes within a liposome to form an oral rehydration solution. At most, the lecithin is used as an emulsifier, a component that promotes the formation and stabilization of an emulsion. There is no teaching or suggestion that the lecithin form lipids containing electrolytes. Moreover, even in combination with Takaichi '235, there is still no teaching or suggestion of such a combination.

Accordingly, one of ordinary skill in the arts, knowing of the cited references would not be able to combine the two to create an oral rehydration solution comprising water and an effective amount of liposomed electrolytes, as is required by the instant application.

Accordingly the instant claims have been patentably distinguished from the cited prior art and therefore the applicant respectfully requests that the examiner withdraw the instant rejection.

Respectfully submitted,



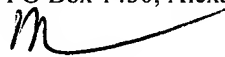
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